K011076

p1/2

JUL 1 6 2001

Summary of Safety and Effectiveness

Administrative Information:

Manufacturer:	Walter Lorenz Surgical, Inc. 1520 Tradeport Drive Jacksonville, FL 32218-2480
Establishment Registration:	1032347
Contact Person:	Kim Reed Regulatory Specialist (904) 741-4400

Devices are manufactured, inspected, packaged, labeled and distributed from the Jacksonville, Florida facility. Walter Lorenz Surgical, Inc. is a wholly owned subsidiary of Biomet, Inc.

Device Name:	Lorenz Sternal Closure System with Modular Screw
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories.
Device Product Code:	87HRS (21 CFR 888.3030)

Substantial Equivalence:

The Lorenz Sternal Closure System with Modular Screw is believed to be substantially equivalent in application and function to the ETHICON Surgical Stainless Steel Suture U.S.P. sizes 5 to 7 and to the Lorenz Reconstruction System with Modular Screw.

The technological features of the devices included in the Lorenz Sternal Closure System with Modular Screw are equivalent to those of the Lorenz Reconstruction System with Modular Screw. These systems share similar features including the: modular screw feature, instrumentation, materials, and add-on plates. Substantial equivalence is based on similarity of the embodiment, function as method of rigid fixation of bone, and on an evaluation of clinical literature which reports mechanical loads in the mandible and in the sternum as similar in magnitude.

This clinical literature includes the study by Ellis *et al.* and the study by Throckmorton *et al.* in which the bite forces of the mandible were measured using an instrumented fixture. A summary can be found on pages 000009 through 000011 of this submision.

The intended use of the devices included in the Lorenz Sternal Closure System is the same as one of the intended uses for the Ethicon Surgical Stainless Steel Suture. The function of both systems is to affix bony fragments of sternum. These systems do not share technological features other than the ability to be cut, if necessary, for emergent re-entry to the chest cavity. Plating of the sternum has been demonstrated to be superior to wiring of the sternum by several clinical and non-clinical studies. A summary can be found on pages 000093 through 000096 of this submission.

Description:
The Lorenz Sternal Closure System with Modular Screw has been designed with a plate having a threaded hole for use with the modular screw and a section to facilitate cutting for rapid re-entry in subsequent thoracic procedures if necessary. The threaded holes have a spherical countersink which allows a standard screw greater angulation as necessary.

The modular screw is a two piece design; a detachable head and a threaded body for insertion into the bone. The detachable head has an inner and outer thread profile. The outer thread profile is for locking the screw head to the plate. The inner thread profile is for detaching and reattaching the head from the threaded body of the screw after insertion into the bone. This allows removal and reattachment of the plate leaving the body of the screw in place.

1.5mm Add-On plates have been designed for use when the defect site includes bone fragments or pieces that require additional stabilization. The Add-On plates attach to the plate using only the modular head or plug. The fixation of the Add-On plate to the bone site requires a 1.5mm screw or 1.8mm screw.

Materials: Plates: CP Titanium Grade II and IV, ASTM F-67
Modular Screw: Ti-6 Al-4V, ASTM F-136
Materials will be specified on the drawing

Intended Use:
The Lorenz Sternal Closure System with Modular Screw is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

Sterility Information:
The Lorenz Sternal Closure System with Modular Screw will be marketed as non-sterile, single use devices. Steam Sterilization recommendations are included in the package insert and can be seen in **TAB 1**.

Possible risks:
The following is a listing of potential risks, which will be included in the package insert:

- Nonunion or delayed union which may lead to breakage of the implant
- Bending or fracture of the implant
- Loosening of the implant
- Metal sensitivities or allergic reaction
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis
- of bone

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 6 2001

Ms. Sheryl Malmberg
Regulatory Manager
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K011076
Trade/Device Name: Lorenz Sternal Closure System with Modular Screw
Regulation Number: 888.3030
Regulatory Class: II
Product Code: HRS
Dated: June 22, 2001
Received: June 25, 2001

Dear Ms. Reed:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K011076

Device Name: Lorenz Sternal Closure System with Modular Screw

Indications For Use:

The Lorenz Sternal Closure System with Modular Screw is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011076

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